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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,323	03/05/2002	Manfred Schmitt	100564-00082	5188

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EXAMINER	
HUFF, SHEELA JITENDRA	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,323	SCHMITT ET AL.	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-39* is/are pending in the application.

4a) Of the above claim(s) *36-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/13/06 has been entered.

Claims 30-39 are pending.

Claims 36-39 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 30-35 are currently under consideration.

The rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of the cancellation of the claim.

The art rejection is withdrawn in view of the amendment.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 30-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in In Re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex Parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the breath of the claims,
5. the amount of direction or guidance present, and
6. the presence or absence of working examples.

The following is an analysis of these factors in relationship to this application.

Nature of the invention

Applicant discloses and claims a method for determining the prognosis of the course of a malignant disease using and antibody that binds to the epitope 52-60 or human uPAR wherein binding is indicative of the a tumor and gives a prognosis for the course of the disease.

State of the Art/ Predictability

Forecasting the outcome of a malignant disease (or prognosis) faces many challenges. Tockman et al, Cancer Research vol. 52 p. 2711s (1992) states that "prior to the successful application of newly described markers, further cross-disciplinary research must (a) refine the selection of biologically appropriate markers, (b) validate such markers against acknowledged disease end points, (c) establish quantitative criteria for marker presence/absence and (d) confirm marker predictive value in

prospective population trials" (abstract). Janicke et al Fibrinolysis vol. 4 p. 69 (1990) indicate that uPA (the antigen for uPAR) is a predictor of early relapse in breast cancer. In order the validate this statement the reference clearly has a cut off value for when uPA is higher that 2.6 ng/mg early relapse is probable whereas then uPA is less than 2.6 ng/mg it is not. The authors of the reference compared the relation of the uPA content in breast cancer tissue to established prognostic factors and to disease free survival. This reference clearly shows the amount of data needed before a claim to prognosis can be substantiated.

Guidance/Working Examples

Applicant has provided one example which is directed to prognostic relevance. The experiment (on page 11 of the specification) compares two ELISA systems (HU277/IIIF10 with HU277/HD13.1) and the results show that the system with the IIIF10 antibody has relevance. The assay was done using breast cancer patients. The data was plotted in Figure 10. This assay clearly has not run all of the appropriate comparisons that have been run in the Janicke et al nor has applicant addressed the concerns raised by Tockman et al. Furthermore, it is not clear what 3.33ng/mg in Figure 10 is referring to. Is this the cut-off between indicating cancer and not?

Breadth of the claims

Applicant is claiming very broadly by claiming that uPAR is a prognostic indicator of all cancers. In view of the above, it is clearly that rigouous testing must be done to establish that a marker can be an indicator for one type of cancer. As discussed above, applicant has not done this testing. Thus, applicant has not enabled the use of uPAR as a prognostic marker for one type cancer, much less all cancers.

In view of the above, it is the Examiner's position that one skilled in the art could not make and/or use the invention without undue experimentation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheela J Huff
Primary Examiner
Art Unit 1643

sjh